REMARKS

Claims 1-3 are pending in the instant application. Claims 1-3 have been rejected. Claims 2 and 3 have been canceled. Claim 1 has been amended. Reconsideration is respectfully requested in light of the following remarks.

I. Rejection of Claims Under 35 U.S.C. §112

Claims 1-3 have been rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The Examiner suggests that the specification does not enable one skilled in the art to prevent motion sickness. Applicants respectfully traverse this rejection.

In an earnest effort to advance the prosecution of this case, Applicants have amended the claims to recite that the method of the instant invention is a method for decreasing the signs and symptoms of motion sickness. Support for this amendment to the claims can be found throughout the specification as filed but in particular a page 5, line 8-10, and Tables 1-2. There data are provided showing that signs and symptoms of motion sickness are decreased significantly with oral administration of a 12 mg dose of chlorpheniramine. Accordingly, the claims as amended clearly meet the requirements of 35 U.S.C. 112, first paragraph. Withdrawal of this rejection is respectfully requested.

II. Rejection of Claims Under 35 U.S.C. 102

Claims 1 and 2 have been rejected under 35 U.S.C. 102(b) as being anticipated by Ueno et al. (1988). The Examiner suggests that this reference discloses treatment of S. murinus by administering 20 mg/kg of chlorpheniramine. Applicants respectfully traverse this rejection.

Ueno et al. (1988) disclose use of several different drugs, including chlorpheniramine, to treat symptoms of motion sickness in an animal model for motion sickness. The chlorpheniramine was administered subcutaneously at a dose of 20 mg/kg. Nowhere does this reference teach use of any other dose of chlorpheniramine, especially not a dose of less than 1 mg/kg.

As discussed *supra*, the claims have been amended to recite that the method of the instant invention involves use of a 12 mg dose of chlorpheniramine. This dose, on a mg/kg basis, represents a dose of less than 1 mg/kg (assuming humans treated with 12 mg and an average body weight of 70 kg). MPEP 2131 is quite clear that in order to anticipate an invention, the cited reference must teach each and every limitation of the claims. The cited reference teaches a much higher dose of chlorpheniramine and, considering the general principles of pharmacology, it would not be obvious to one of skill that a much lower dose, more than an order to magnitude lower, would be as effective. Accordingly, this reference fails to teach or suggest the invention of the claims as amended, and withdrawal of this rejection is respectfully requested.

Claims 1 and 2 have been rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,624,965. The Examiner suggests that this patent discloses a method of administering a

known anti-emetic such as brompheniramine nasally for treating nausea induced by motion sickness. Applicants respectfully traverse this rejection.

U.S. Patent No. 4,624,965 discloses administration of therapeutic agents nasally as anti-emetic and anti-nausea agents. Brompheniramine is mentioned as one a group of selected agents. The patent teaches administration of from 5 to 75 mg of the agents nasally. However, the only data provided showing the actual anti-nausea effects of drugs are for metoclopramide or diphenhydramine. Nowhere does this patent teach or suggest administration of any agent by a route other than intranasally.

As discussed *supra*, the claims have been amended to recite that the method of the instant invention involves use of a 12 mg dose of chlorpheniramine, and administering the drug either orally or topically. MPEP 2131 is quite clear that in order to anticipate an invention, the cited reference must teach each and every limitation of the claims. The cited reference teaches use of different specific drugs and their use intranasally. Accordingly, this reference fails to teach or suggest the invention of the claims as amended, and withdrawal of this rejection is respectfully requested.

Claims 1-3 have been rejected under 35 U.S.C. 102(b) as being anticipated by Peterlin et al. (1998). The Examiner suggests that this reference teaches a method of orally administering chlorpheniramine to humans. Applicants respectfully traverse this rejection.

Peterlin et al. (1998) disclose the effects of use of oral chlorpheniramine on responses in an exercise tolerance test. The specific responses measured before and after drug treatment

included total peripheral resistance and oxygen uptake. The reference discloses use of a typical over-the-counter dose of chlorpheniramine, mentioned to be 4 mg. No other dose of chlorpheniramine is taught, nor is the effect of the drug on any endpoint other than the exercise tolerance endpoints.

As discussed *supra*, the claims have been amended to recite that the method of the instant invention involves use of a 12 mg dose of chlorpheniramine, and administering the drug either orally or topically. MPEP 2131 is quite clear that in order to anticipate an invention, the cited reference must teach each and every limitation of the claims. The cited reference teaches use of a lower dose of chlorpheniramine for an entirely different use, and it would not be obvious to one of skill that a different dose would be as effective, particularly when the drug is being administered to affect very different endpoints (signs and symptoms of motion sickness, not exercise tolerance). The general principles of pharmacology dictate that different endpoints of efficacy can exhibit different dose-response relationships. Accordingly, this reference fails to teach or suggest the invention of the claims as amended, and withdrawal of this rejection is respectfully requested.

III. Conclusion

The Applicants believe that the foregoing comprises a full and complete response to the Advisory Action of record.

Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,

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